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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------------------------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/617,967 | 07/10/2003 | Willard M. Welch | PC11002B | 4135 |
| 23913 | 7590 | 08/25/2004 | EXAMINER | |
| PFIZER INC 150 EAST 42ND STREET 5TH FLOOR - STOP 49 NEW YORK, NY 10017-5612 | | | BERNHARDT, EMILY B | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1624 | |

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

10/617,967

Applicant(s)

WELCH ET AL.

Examiner

Emily Bernhardt

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4 is/are allowed.
- 6) ☒ Claim(s) 1,3,5-12 is/are rejected.
- 7) ☒ Claim(s) 2 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

In view of applicants' response filed 5/27/04 the following still applies.

Claims 1,3,5-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Note that claims 2 and 4 were inadvertently included in the previous action.

1. There is a typographical error in formula (I) in claim 1 as now amended. Note 2 R^2 's in the formula vs. R^2 and R^3 .
2. Composition claims 5 and 7 remain substantial duplicates as well as newly presented claims 9 vs 11 which each depend on claim 4. It is not evident from a reading of the specification that any one composition is specially adapted for one use vs another. Thus it remains unclear how one can infringe one of the pairs of these claims without infringing the other.
3. Method claims 6 vs 8 as well as new claims 10 vs 12 are also duplicate pairs. Applicants traverse to this rejection is even less clear since no compositions are included.

Claims 1-3, 5-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled

in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Reasons #1 and 2 of the previous action are maintained. With regard to reason #1 Given the many factors that do pertain in the instant case as discussed in previous actions there is reason to question efficacy of the instant scope given the **homogeneity** of the prepared examples coupled with the lack of any test data (just an inference that compounds were tested). As there is no test data reported and thus no structure-activity trends that can be evaluated more than undue experimentation is required to determine which permutations out of the billions claimed might be suitable to practice the invention.

With regard to reason #2 references provided by applicant support the examiner's position since the same uses indicated as enabled in the previous action are the ones most clearly correlated to instant activity as discussed in the Glennon article. See p.22. The remaining reference consists of an Abstract page which appears to be discussing potential uses, especially migraine, but the focus appears to be developing lead compounds that are 5-HT₇ antagonists. Applicants' compounds are stated to be selective agonists. Additionally, note Genentech vs. Novo Nordisk 42 USPQ 2d 1001 especially left column at p.1005 which states the following: "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may be

workable.” . In the same decision at p.1004 it is clearly stated that “to be enabling the specification must teach ... how to make and use the full scope of the claimed invention without undue experimentation.”

Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 4 is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is (571) 272-0664.

If attempts to reach the examiner by phone are unsuccessful, the supervisor for AU 1624, Dr. Mukund Shah, can be reached at (571)272-0674.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.



EMILY BERNHARDT

PRIMARY EXAMINER

Group 1600